IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Serial No.	:	**10/783,897**
Filed	:	February 20, 2004
Applicants	:	John T. Santini Jr., et al.
Title	:	Medical Device with Controlled Reservoir Opening
TC/AU	:	3763
Examiner	:	Vu, Quynh-Nhu Hoang
Docket No.	:	17648-0027 (MIT6962 CIP2CON)
Customer No.	:	29052

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.191 and M.P.E.P. § 1205, Applicants appeal the Examiner's final rejection of all pending claims in the referenced application. Authorization to charge the fee of $510.00 required under 37 C.F.R. § 41.20(b)(2) to Deposit Account 19-5029 is submitted herewith.

This Brief follows the Notice of Appeal filed May 15, 2008. A Petition for Extension of Time under 37 C.F.R. § 1.136 is submitted herewith to extend the time for submission of this Brief by two months, to September 15, 2008.

I. Real Party in Interest

The real party in interest in this appeal is the Massachusetts Institute of Technology, a corporation of the Commonwealth of Massachusetts, having a principal place of business at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139. This corporation is the assignee of the full, exclusive and entire right, title, and interest in the referenced application. The assignments of the great-grandparent patent application, Serial No. 08/675,375, are recorded at the U.S. Patent and Trademark Office at Reel 008242, Frame 0537 and at Reel 008243, Frame 0173. The assignment of the grandparent patent application, Serial No. 09/022,322, is recorded at the U.S. Patent and Trademark Office at Reel 009082, Frame 0949. The assignment of the parent application, Serial No. 09/665,303, is recorded at the U.S. Patent and Trademark Office at Reel 011326, Frame 0154. These assignments apply to the present application.

II. Related Appeals and Interferences

An appeal is pending for Application Serial No. 11/041,161, a sibling of the present application. The Notice of Appeal was filed on June 9, 2008. Like the present application, Serial No. 11/041,161 is a continuation of U.S. Application No. 09/665,303, filed September 19, 2000, now U.S. Patent No. 7,070,590, which is a continuation-in-part of U.S. Application No. 09/022,322, filed February 11, 1998, now U.S. Patent No. 6,123,861, which is a continuation-in-part of U.S. Application No. 08/675,375, filed July 2, 1996, now U.S. Patent No. 5,797,898.

III. Status of Claims

Claims 55-103 are pending and stand finally rejected as set forth in the Office Action mailed February 15, 2008 ("Final Office Action"). Claims 1-54 are canceled. The rejections of claims 55-103 are being appealed.

IV. Status of Amendments

No amendments have been filed subsequent to the Final Office Action.

V. Summary of Claimed Subject Matter

The claimed subject matter is drawn to devices as set forth in independent claims 55, 69, 77, 91, and 97, and in claims dependent on these independent claims.

Independent claim 55 is drawn to an implantable medical device for the controlled release of drug molecules. The claimed device includes (i) a substrate (Pg. 6, Lns. 2-3; Pg. 6, Ln. 6 – Pg. 7, Ln. 1; Fig. 5, part 160; Figs. 8a-c); (ii) at least two reservoirs in the substrate (Pg. 2, Lns. 28-29; Pg. 6, Lns. 2-3); (iii) a release system disposed in the reservoirs, the release system comprising drug molecules for release (Pg. 6, Lns. 2-3; Pg. 7, Ln. 2 – Pg. 8, Ln. 24; Fig. 5, part 180; Figs. 8a-c); and (iv) discrete metal reservoir caps positioned over or within openings in the reservoirs (Fig. 5, part 120; Figs. 8a-c), wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir cap is actively controlled (Pg. 6, Lns. 3-4; Pg. 21, Ln. 23 – Pg. 22, Ln. 14).

Independent claim 69 is drawn to a microchip device for the controlled release of drug molecules. The claimed device includes (i) a substrate (Pg. 6, Lns. 2-3; Pg. 6, Ln. 6 – Pg. 7, Ln. 1; Fig 5, part 160; Figs. 8a-c); (ii) at least two reservoirs in the substrate, wherein each reservoir has at least one opening defined in the substrate (Pg. 2, Lns. 28-29; Pg. 6, Lns. 2-3; Figs. 9A-C); (iii) release system disposed in the reservoirs, the release system comprising drug molecules for release (Pg. 6, Lns. 2-3; Pg. 7, Ln. 2 – Pg. 8, Ln. 24; Fig. 5, part 180; Figs. 8a-c); and (iv) at least two discrete electrically conductive reservoir caps, each reservoir cap closing off the opening defined by a respective reservoir (Fig. 5, part 120; Figs. 8a-c), wherein release of the drug

molecules from the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap (Pg. 6, Lns. 3-4; Pg. 21, Ln. 23 – Pg. 22, Ln. 14).

Independent claim 77 is drawn to a medical device. The claimed device includes (i) a substrate (Pg. 6, Lns. 2-3; Pg. 6, Ln. 6 – Pg. 7, Ln. 1; Fig 5, part 160; Figs. 8a-c); (ii) at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate (Pg. 2, Lns. 28-29; Pg. 6, Lns. 2-3; ; Fig. 5; Figs. 9A-C); (iii) discrete reservoir caps covering the at least two reservoirs (Pg. 6, Lns. 3-4; Pg. 21, Ln. 23 – Pg. 22, Ln. 14; Fig. 5; Figs. 8a-c); and (iv) control circuitry for selectively disintegrating the reservoir caps to open the reservoirs (Pg. 6, Ln. 5; Pg. 18, Ln. 24 – Pg. 22, Ln. 14).

Independent claim 91 is drawn to a device for use in medical diagnostics. The device includes (i) a substrate (Pg. 6, Lns. 2-3; Pg. 6, Ln. 6 – Pg. 7, Ln. 1); (ii) at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate (Pg. 2, Lns. 28-29; Pg. 6, Lns. 2-3; Fig. 5; Figs. 9A-C); (iii) a diagnostic reagent disposed in the reservoirs (Pg. 9; Lns. 5-11); (iv) discrete reservoir caps covering the at least two reservoirs (Pg. 6, Lns. 3-4; Pg. 21, Ln. 23 – Pg. 22, Ln. 14); and (iv) control circuitry for selectively disintegrating the reservoir caps to open the reservoirs (Pg. 6, Ln. 5; Pg. 18, Ln. 24 – Pg. 22, Ln. 14).

Independent claim 97 is drawn to a medical device. The device includes (i) a substrate (Pg. 6, Lns. 2-3; Pg. 6, Ln. 6 – Pg. 7, Ln. 1); (ii) at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate (Pg. 2, Lns. 28-29; Pg. 6, Lns. 2-3; Fig. 5; Figs. 9A-C); (iii) discrete reservoir caps covering the at least two reservoirs (Pg. 6, Lns. 3-4; Pg. 21, Ln. 23 – Pg. 22, Ln. 14); and (iv) control circuitry for selectively disintegrating the reservoir caps to open the reservoirs, wherein the reservoir cap disintegration comprises

dissolving into solution, or forming soluble ions or oxidation compounds, upon application of an electric potential generated by the control circuitry (Pg. 6, Lns. 3-4; Pg. 18, Ln. 24 – Pg. 22, Ln. 14).

VI. Grounds of Rejection to Be Reviewed On Appeal

The following grounds of rejection are presented for review:

Ground No. 1

Whether the description in the specification of the subject matter of claims 58 and 61 satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

Ground No. 2

Whether a *prima facie* case of anticipation has been established to support a rejection of claims 77-103 over U.S. Patent No. 5,366,454 to Currie et al. ("Currie").

Ground No. 3

Whether a *prima facie* case of obviousness has been established to support a rejection of claims 55-76, 85, and 94 over Currie.

VII. Argument

A. Background

Appellants' claims are directed to devices having multiple, tiny, containment reservoirs that can be opened at a selected time by causing the disintegration of individual reservoir caps that cover the reservoirs' openings. The devices may be a medical device, such as an implantable medical device, for example, for the controlled delivery of drug molecules, or for use in medical diagnostics. The claimed devices require a substrate, at least two reservoirs in the

substrate, and discrete reservoir caps positioned over, or within, or covering, the at least two reservoirs.

All of Appellants' claims recite reservoir caps that are selectively disintegrable. Claims 55-76 require discrete metal or electrically conductive reservoir caps, wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap. Claims 77-103 require control circuitry for selectively disintegrating the reservoir caps to open the reservoirs.

B. Ground No. 1

The rejection of claims 58 and 61 for failure to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, is erroneous. The specification contains a written description of the invention of claims 58 and 61 sufficient to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Moreover, the Examiner has failed to meet his initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). An applicant's description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g.*, In re Marzocchi, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971); M.P.E.P. § 2163. Here, the Examiner has identified no evidence that the claimed devices lack sufficient disclosure for one skilled in the art to practice the invention. The Examiner also has articulated no well-reasoned basis to allege that one skilled in the art—who has read Appellants' disclosure and who already possesses information known in the art—would require undue experimentation to make or use Appellants' claimed devices.

Claim 58 is enabled.

Claim 58 specifies that "a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir." An embodiment is illustrated in Figure 9C of the original specification, with reference to the accompanying text at page 33, lines 16-20, which recites "Top substrate portion 710a has reservoir 720a which is in communication with reservoir 720b in bottom substrate portion 710b." Thus, there is an upper reservoir section (720a) in communication with a lower reservoir section (720b) forming a single reservoir (the shaded area of 720a/720b). The description fully enables one of ordinary skill in the art to make and use the invention.

Claim 61 is enabled.

Claim 61 specifies that an "internal reservoir cap is disintegratable, so that the two reservoir sections become a single reservoir upon disintegration of the internal reservoir cap." An embodiment of claim 61 is illustrated in Figure 9D and accompanying text at page 33, line 24 to page 34, line 9 of the original specification. Figure 9D shows an internal reservoir cap (830b) that is disintegratable so that the two reservoir sections (840a and 840b) become a single reservoir (the shaded area of 840a/840b) upon disintegration of the internal reservoir cap. The description fully enables one of ordinary skill in the art to make and use the invention.

No *prima facie* case of lack of enablement has been made for claim 58 or 61.

The Examiner fails to present sufficient evidence or reasoning to rebut the presumption that Appellants' claims are enabled, and thus fails to establish a *prima facie* case for lack of enablement. The Examiner erroneously argues that the specification does not enable these

claims 58 and 61 because "applicants do not disclose how/what make two reservoirs formed a single reservoir." (Final Office Action, p. 2). The Examiner further argues that "According to Fig. 9c, it shows that there is only one/single reservoir." (Final Office Action, p. 2). In a contradictory statement on page 7 of the same Office Action, the Examiner maintains that "Figs. 9c-9d or in the specification on page 33, line 16-page 34, line 3 do not disclose the limitation that 'the two reservoir sections formed a single reservoir' as in claims 58 and 61." (Final Office Action, p. 7).

Appellants' claims do not specify two reservoirs forming a single reservoir, but instead specify two reservoir sections forming a single reservoir. Appellants describe a device comprising two reservoir sections forming a single reservoir on page 3, lines 1-6 of the specification, reciting the language of claims 58 and 61 almost verbatim:

> In a preferred embodiment, the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap, *such that a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir* which generally is larger than that which would be provided using the single substrate device. (emphasis added).

Coupled with other details found throughout Appellants' specification (e.g., P. 10, Ln. 11 – P. 12, Ln. 30; P. 21, Ln. 2 – P. 22, Ln. 14), one skilled in the art would not require undue experimentation to be able to bond top and bottom substrate portions together, or to fill the reservoirs (e.g., 720a/720b) with molecules for release, or to cover the reservoirs with reservoir caps, or to seal the reservoirs with a backing plate. Thus, Appellants' specification fully describes two reservoir sections forming a single reservoir, such that a person of ordinary skill

can readily duplicate it. No sound technical reason or evidence has been presented by the Examiner to doubt that one of ordinary skill in the art—who is not an automaton, but instead who possesses ordinary creativity and common sense (see KSR Int'l Co. v. Teleflex, Inc., 550 U.S. __, 127 S. Ct. 1727, 1742 (2007))—can make and use two reservoir sections forming a single reservoir without undue experimentation. The Examiner has failed to meet his initial burden to establish a *prima facie* case for lack of enablement.

C. Ground No. 2

The rejection of claims 77-103 over Currie is erroneous. A proper *prima facie* case of anticipation has not been established to support the rejection.

Claims 77-103 are novel over Currie.

Currie discloses an implantable medication dispensing device having a plurality of compartments containing medicine, each compartment having a delivery opening permitting delivery of the medicine. (Currie, Col. 1, Lns. 59-64). A rupturable membrane having a predetermined elastic deformation limit and a predetermined rupture point seals the delivery opening of each compartment. (Currie, Col. 1, Lns. 64-67). The rupturable membrane is formed of silicon. (Currie, Col. 5, Lns. 54-58). A stress-inducing means is applied to the membrane to maintain the membrane stressed substantially to its elastic deformation limit. (Currie, Col. 2, Lns. 2-5). Also attached to the rupturable membrane is a rupturing system including a piezoelectric transducer that mechanically deforms upon application of a voltage between certain faces of the material. (Currie, Col. 1, Ln. 67 – Col. 2, Ln. 8). Upon application of an electrical signal, the piezoelectric transducer mechanically deforms and applies sufficient additional stress to the rupturable membrane to cause the membrane to rupture. (Currie, Col. 2, Lns. 5-13).

"Examples of suitable piezoelectric materials which can be used in the . . . invention are lead zirconate titanate, zinc oxide and cadmium sulphide." (Currie, Col. 2, Lns. 32-35). It is understood that these three disclosed materials are all crystalline, ceramic-type piezos. Due to the likelihood that the rupture of the silicon membrane into pieces will release fragments of the membrane into the body, Currie provides for a bio-compatible polymeric film encapsulating the dispenser. (Currie, Col. 6, Lns. 66-67). The biocompatible polymeric film covers "the membrane rupturing zone defined between the assemblies 26a and 26b [of Fig. 4] so as to bind any broken membrane fragments and prevent the same from being released into the animal or human." (Currie, Col. 6, Ln. 67 – Col. 7, Ln. 3). In short, the pre-stressed silicon membranes of Currie are opened via a mechanical mechanism, relying upon piezoelectric transducers for applying sufficient additional stress to cause the membranes to rupture. The rupturing of the membranes is caused by the external application of mechanical stress to the membranes.

Appellants' claims 77-103 require that the reservoir caps are selectively disintegrable. Disintegrating Appellants' reservoir caps is not the same as rupturing Currie's fragile membrane. The rupturing in Currie is purely mechanical, and Currie even provides a polymeric film to trap the shards of ruptured membrane. (Currie, Col. 6, Ln. 67 – Col. 7, Ln. 3). In contrast, Appellants' claimed invention recites "disintegrating the reservoir caps." An example of reservoir cap disintegration includes dissolution into solution, or formation of soluble ions or oxidation compounds, upon application of an electric potential generated by control circuitry. For instance, Appellants' specification provides that:

> When an electric potential is applied between an anode and cathode, the conductive material of the anode above the reservoir oxidizes to form soluble compounds or ions that dissolve into solution, exposing the release system

> containing the molecules to be delivered to the surrounding fluids. Alternately, the application of an electric potential can be used to create changes in local pH near the anode reservoir cap to allow normally insoluble ions or oxidation products to become soluble. This would allow the reservoir cap to dissolve and expose the release system to the surrounding fluids.

(Pg. 22, Lns. 1-8). Appellants' original specification at page 4, lines 3-6 also states that the reservoir caps are formed of "materials that passively disintegrate, . . . or materials that disintegrate upon application of an electric potential." Appellants' mechanism of molecular scale disintegration, such as a phase change or chemical reaction, is different from the macroscale, mechanical fragmentation of Currie's rupture mechanism. Since Currie fails to disclose Appellants' claimed feature of disintegrating the reservoir caps, the claims are not anticipated.

Claims 85 and 94 are novel over Currie.

Furthermore, Appellants' claims 85 and 94 recite that "the reservoir caps comprise a metal film." The reservoir cap is the structure that closes off the reservoir opening and that disintegrates to open the reservoir. The only analogous structure in Currie is a silicon membrane. A silicon membrane is not a metal film. Currie does not teach that the silicon membrane includes a metal film. The Examiner explicitly conceded at page 5 of the Office Action mailed August 24, 2007 that "Currie does not disclose the reservoir cap formed of metal." Yet, the Examiner persists with the rejection. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). An element is not "inherent" in the disclosure of a

prior art reference unless extrinsic evidence makes clear that the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999). "Inherency . . . may not be established by probabilities or possibilities." Id. Currie fails to disclose that the rupturable membrane necessarily is a metal film, and the Examiner has provided no evidence or reasoning to support even an inference that the rupturable membrane necessarily is a metal film. Because Currie neither expressly nor inherently discloses reservoir caps comprising a metal film, the reference does not anticipate Appellants' claims 85 and 94.

Claims 97 and 98 are novel over Currie.

In addition, the anticipation rejection of claims 97 and 98 is meritless. These claims expressly require that the reservoir cap disintegration include "dissolving into solution, or forming soluble ions or oxidation compounds upon application of an electrical potential generated by the control circuitry." The Examiner references Figure 6 as providing the alleged anticipation (Final Office Action, P. 3). However, Figure 6 and its description are irrelevant to this element of Appellants' claim. In fact, nothing in Currie mentions dissolution or oxidation being part of the membrane rupturing mechanism, and nothing in Currie teaches a rupturing mechanism that involves dissolution or oxidation induced by application of an electric potential.

D. Ground No. 3

The rejection of claims 55-76, 85, and 94 over Currie is erroneous. A proper *prima facie* case of obviousness has not been established to support the rejection.

Claims 55-76, 85, and 94 require disintegratable reservoir caps. Currie fails to teach or suggest disintegratable reservoir caps. As discussed above in Part C, Currie discloses a pre-

stressed silicon membrane covering openings of a plurality of medicine-containing compartments. Currie also provides a piezoelectric transducer that mechanically deforms upon application of an electric potential. The mechanical deformation of the piezoelectric transducer applies additional stress to the pre-stressed, brittle silicon membrane, causing the membrane to rupture. In contrast, Appellants' mechanism involves molecular scale disintegration, rather than macroscale mechanical rupture, of the reservoir cap. Appellants' reservoir cap disintegration includes dissolution into solution, or formation of soluble ions or oxidation compounds, upon application of an electric potential generated by control circuitry. The Federal Circuit has made clear that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). The Examiner here has failed to articulate with any clarity how Currie is alleged to render obvious the disintegratable reservoir caps of Appellants' claims. Because the Examiner has failed to explain some rational underpinning to support the obviousness conclusion, the Examiner has failed to establish a *prima facie* case of obviousness. Thus, the rejection must fail.

In addition to failing to teach or suggest disintegratable reservoir caps, Currie also fails to teach or suggest metal or electrically conductive reservoir caps. Independent claim 55 and dependent claims 56-68 require "discrete metal reservoir caps." Independent claim 69 and dependent claims 70-76 require "electrically conductive reservoir caps." Dependent claims 85 and 94 require reservoir caps comprising a "metal film." As discussed above in Part C, Currie discloses only silicon membranes and does not disclose or suggest metal or electrically conductive reservoir caps. (Currie, Col. 5, Lns. 54-58). Silicon is not a metal and silicon is not

a conductor. The Examiner specifically conceded at page 5 of the Office Action mailed August 24, 2007 that "Currie does not disclose the reservoir cap formed of metal." The mechanical rupture mechanism of Currie relies on the inherent brittleness or fragility of the silicon membrane. When additional stress is applied to the pre-stressed silicon membrane by the piezoelectric transducer, the brittle membrane ruptures into fragments to release the drug. Metal or electrically conductive materials are ductile, so one of ordinary skill in the art starting with Currie would have no reason to remove the thin, brittle silicon membrane and replace it with a metal reservoir cap. Moreover, because the mechanism of Currie does not require the passage of electricity through the reservoir cap, one of ordinary skill in the art starting with Currie would have no reason to replace the silicon membrane with an electrically conductive material.

The Examiner's reasoning is both legally and factually incorrect. The Examiner reasons, as can be best understood by Appellants, that Currie's disclosure that the silicon membrane is anodically bonded to the silicon body means that the silicon membrane can be used as an anode material. (Final Office Action, Pg. 4). The Examiner cites U.S. Patent No. 6,537,938 to Miyazaki ("Miyazaki") as evidence that in anodic bonding silicon is used as an anode. (Final Office Action, Pg. 8). Further, since the silicon membrane allegedly can be used as an anode, and since Appellants disclose that the conductive metal reservoir caps serve as anodes, it allegedly would be obvious to substitute metal for the silicon membrane in Currie. Moreover, the Examiner reasons that since silicon and metal allegedly can serve as anode material in electrochemical cells, as evidenced by U.S. Patent No. 4,623,597 to Auborn ("Auborn") or U.S. Patent No. 4,623,597 to Sapru et al. ("Sapru"), it would be obvious to substitute metal for the silicon membrane in Currie. The Examiner's hindsight-driven conjecture lacks a sound legal or factual basis.

First, the Examiner's reasoning is legally insufficient. The Examiner's reasoning relying upon Appellants' teaching that the conductive metal reservoir caps serve as anodes is the very pinnacle of hindsight reasoning that is prohibited. The Examiner uses Appellants' own disclosure against them. Appellants' disclosure is not part of the prior art and Appellants' disclosure of conductive metal anodes cannot be used as a motivation for searching in the prior art for piecemeal elements from the wholly unrelated, non-analogous area of batteries to use against them. Thus, the rejection is legally improper and insufficient.

Second, the Examiner's reasoning is factually incorrect. Currie's disclosure of anodic bonding does not mean that the silicon membrane "can be used as an anode material." Although Currie does disclose that the silicon reservoir membrane is anodically bonded to the silicon body, the Examiner's reasoning is incorrect because anodic bonding is understood in the art of microfabrication to refer to a specific method of bonding two materials together. Anodic bonding of silicon to silicon wafer utilizes Pyrex glass as an intermediary and requires a negative cathode coupled to the Pyrex glass and a positive anode coupled to a first silicon wafer. A large voltage is applied between the electrodes to create migration of sodium cations in the glass towards the cathode, leaving a negative charge at the interface, which, as the electrons from the silicon wafer are drawn to the anode, attracts the silicon cations from the silicon wafer to form a strong SiO_2 interface to bond the silicon wafer to the glass. By bonding another silicon wafer to the opposite side of the Pyrex glass interlayer in the same manner, the two silicon wafers are joined together. (*See, e.g.*, Marc J. Madou, Fundamentals of Microfabrication: The Science of Miniaturization 484-86 (CRC Press, 2d ed. 2002)) (attached as Appendix 2 – Evidence).

Furthermore, the Examiner incorrectly cites Miyazaki as evidence that in anodic bonding silicon is used as an anode. One of ordinary skill in the art reading Miyazaki as a whole would not read the reference to disclose the use of silicon as an anode. The portion cited by the Examiner is contrary to the remainder of the reference and the knowledge in the art. In the portion relied upon by the Examiner, Miyazaki contradicts himself by first stating that the glass is used as a cathode and then by stating that cations in the glass move to the cathode. (Miyazaki, Col. 1, Lns. 32-34). At column 4, line 65 to column 5, line 2, Miyazaki describes and illustrates separate electrodes to anodically bond silicon and glass. One of ordinary skill in the art reading Miyazaki would understand that in anodic bonding the silicon and glass are not used as electrodes, but rather a separate anode and cathode are required for anodic bonding to occur. The disclosure of Currie, read alone or in combination with Miyazaki, does not, under any interpretation by one of ordinary skill in the art, mean that the silicon membrane can be used as an anode material.

In addition, the Examiner's reasoning is factually incorrect because neither Auborn nor Sapru provide evidence that the silicon membrane disclosed in Currie can be used as an anode material. The Examiner misinterprets Auborn and Sapru. Auborn discloses as an anode a metal and silicon alloy. Sapru discloses an anode comprising a disordered multicomponent material formed of a host matrix element, which may be silicon, and modifier elements. Thus, both Auborn and Sapru disclose anodes requiring silicon and another material, whereas Currie discloses a membrane comprising only silicon. One of ordinary skill in the art would not read Currie, alone or in combination with another reference, to disclose a silicon membrane that can function as an anode.

Finally, if the Examiner is implying that one of ordinary skill in the art would have been motivated to reinforce the silicon membrane of Currie with a layer of metal, then Appellants observe that such a structure would be contradictory to Currie's need for the membrane to be brittle and easily rupturable. Hence, one of ordinary skill in the art would not have had a reason at the time of Appellants' invention to modify Currie's device and derive Appellants' device—which utilize an entirely distinct mechanism of opening containment reservoirs.

In sum, the cited prior art, when considered as a whole for all that it teaches, fails to teach or suggest the claimed combination of elements defining Appellants' claimed devices. No *prima facie* case of anticipation or obviousness has been established based on the prior art. The rejections are therefore improper and should be reversed.

VIII. Claims Appendix

The appendix containing a copy of the claims involved in the appeal can be found on page 19.

IX. Evidence Appendix

The following evidence was entered by the examiner and is relied upon by appellant in the appeal:

> Marc J. Madou, Fundamentals of Microfabrication: The Science of Miniaturization 484-86 (CRC Press, 2d ed. 2002).

This evidence was submitted with Applicant's Response to Office Action dated May 15, 2008 and was considered by the Examiner, as indicated in the Advisory Action mailed on May 28, 2008. A copy of the evidence is submitted herewith in the appendix for evidence on page 28.

X. Related Proceedings Appendix

The appendix for related proceedings can be found at page 29. No decisions have been rendered by a court or the Board in the proceedings identified in Part II pursuant to 37 C.F.R. § 41.37(c)(1)(ii).

Respectfully Submitted,

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Date: August 25, 2008

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APPENDIX 1 – CLAIMS ON APPEAL

1-54. (Canceled).

55. (Previously presented). An implantable medical device for the controlled release of drug molecules comprising:

a substrate;

at least two reservoirs in the substrate;

release system disposed in the reservoirs, the release system comprising drug molecules for release; and

discrete metal reservoir caps positioned over or within openings in the reservoirs,

wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir cap is actively controlled.

56. (Previously presented). The device of claim 55, wherein the substrate is comprised of two or more substrate portions bonded together.

57. (Previously presented). The device of claim 56, wherein the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap.

58. (Previously presented). The device of claim 57, wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir.

59. (Previously presented). The device of claim 57, wherein the reservoir section in the lower substrate portion has a volume that is greater than the volume of the reservoir section in the upper substrate portion.

60. (Previously presented). The device of claim 57, wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.

61. (Previously presented). The device of claim 60, wherein the internal reservoir cap is disintegratable, so that the two reservoir sections become a single reservoir upon disintegration of the internal reservoir cap.

62. (Previously presented). The device of claim 60, wherein the reservoir section of the lower substrate portion contains molecules different in quantity, type, or both quantity and type, from the molecules contained in the reservoir section of the upper substrate portion.

63. (Previously presented). The device of claim 55, wherein disintegration of the reservoir cap is activated by application of electrical energy through the reservoir cap.

64. (Previously presented). The device of claim 63, wherein at least one reservoir cap is an anode, and the device further comprises a cathode, a power source, and electrical circuitry means

for application of an electric potential between the cathode and anode effective to disintegrate the reservoir cap.

65. (Previously presented). The device of claim 55, wherein the release system further comprises at least one matrix material, excipient, or combination thereof.

66. (Previously presented). The device of claim 55, wherein the release system further comprises at least one biodegradable or bioerodible polymeric material.

67. (Previously presented). The device of claim 55, wherein the drug molecules comprise anesthetics, vaccines, chemotherapeutic agents, metabolites, immunomodulators, antioxidants, antibiotics, and ion channel regulators, or hormones.

68. (Previously presented). The device of claim 55, wherein the disintegration of at least one of the reservoir caps is controlled by a signal from a biosensor or by a preprogrammed microprocessor.

69. (Previously presented). A microchip device for the controlled release of drug molecules comprising:

a substrate;

at least two reservoirs in the substrate, wherein each reservoir has at least one opening defined in the substrate;

release system disposed in the reservoirs, the release system comprising drug molecules for release; and

at least two discrete electrically conductive reservoir caps, each reservoir cap closing off the opening defined by a respective reservoir,

wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap.

70. (Previously presented). The device of claim 69, wherein the substrate is comprised of two or more substrate portions bonded together.

71. (Previously presented). The device of claim 69, wherein at least one reservoir cap is an anode, and the device further comprises a cathode, a power source, and electrical circuitry means for application of an electric potential between the cathode and anode effective to disintegrate the reservoir cap.

72. (Previously presented). The device of claim 69, wherein the release system in at least one of the reservoirs differs in quantity, type, or both quantity and type, from the release system in at least one other of the reservoirs.

73. (Previously presented). The device of claim 69, wherein the release system further comprises at least one matrix material, excipient, or combination thereof.

74. (Previously presented). The device of claim 69, wherein the release system further comprises at least one biodegradable or bioerodible polymeric material.

75. (Previously presented). The device of claim 69, wherein the reservoir caps are formed of a metal film.

76. (Previously presented). The device of claim 70, wherein the drug molecules comprise anesthetics, vaccines, chemotherapeutic agents, metabolites, immunomodulators, antioxidants, antibiotics, and ion channel regulators, or hormones.

77. (Previously presented). A medical device comprising:

a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

discrete reservoir caps covering the at least two reservoirs; and

control circuitry for selectively disintegrating the reservoir caps to open the reservoirs.

78. (Previously presented). The device of claim 77, wherein the reservoirs comprise molecules useful in medical diagnostics.

79. (Previously presented). The device of claim 78, wherein the molecules comprise a diagnostic reagent.

80. (Previously presented). The device of claim 78, wherein the molecules are bioactive.

81. (Previously presented). The device of claim 77, wherein the substrate comprises silicon.

82. (Previously presented). The device of claim 77, wherein the substrate comprises two or more layers or portions bonded together.

83. (Previously presented). The device of claim 82, wherein the substrate comprises layers of silicon, glasses, ceramics, semiconductors, metals, polymers, or a combination thereof.

84. (Previously presented). The device of claim 77, further comprising a biosensor.

85. (Previously presented). The device of claim 77, wherein the reservoir caps comprise a metal film.

86. (Previously presented). The device of claim 77, wherein the reservoir cap comprises an anode and the control circuitry comprises a cathode and a power source for creating an electric potential between the cathode and the anode.

87. (Previously presented). The device of claim 77, wherein reservoir opening is controlled by a signal from a biosensor or by a preprogrammed microprocessor.

88. (Previously presented). The device of claim 77, wherein the control circuitry comprises a cathode, a microprocessor, a timer, a demultiplexer, and a power source, wherein at least one reservoir cap is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

89. (Previously presented). The device of claim 77, which is adapted for implantation into a patient.

90. (Previously presented). The device of claim 77, wherein the reservoirs comprise drug molecules.

91. (Previously presented). A device for use in medical diagnostics comprising:

a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

a diagnostic reagent disposed in the reservoirs;

discrete reservoir caps covering the at least two reservoirs; and

control circuitry for selectively disintegrating the reservoir caps to open the reservoirs.

92. (Previously presented). The device of claim 91, wherein the substrate comprises two or more layers or portions bonded together.

93. (Previously presented). The device of claim 92, wherein the substrate comprises layers of silicon, glasses, ceramics, semiconductors, metals, polymers, or a combination thereof.

94. (Previously presented). The device of claim 91, wherein the reservoir caps comprise a metal film.

95. (Previously presented). The device of claim 91, wherein the reservoir cap comprises an anode and the control circuitry comprises a cathode and a power source for creating an electric potential between the cathode and the anode.

96. (Previously presented). The device of claim 91, wherein reservoir opening is controlled by a signal from a biosensor or by a preprogrammed microprocessor.

97. (Previously presented). A medical device comprising:

a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

discrete reservoir caps covering the at least two reservoirs; and

control circuitry for selectively disintegrating the reservoir caps to open the reservoirs,

wherein the reservoir cap disintegration comprises dissolving into solution, or forming soluble ions or oxidation compounds, upon application of an electric potential generated by the control circuitry.

98. (Previously presented). The medical device of claim 97, wherein the control circuitry comprises a cathode and a power source, wherein at least one reservoir cap is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

99. (Previously presented). The device of claim 97, wherein the reservoirs comprise molecules useful in medical diagnostics.

100. (Previously presented). The device of claim 99, wherein the molecules comprise a diagnostic reagent.

101. (Previously presented). The device of claim 97, wherein the reservoirs comprise drug molecules.

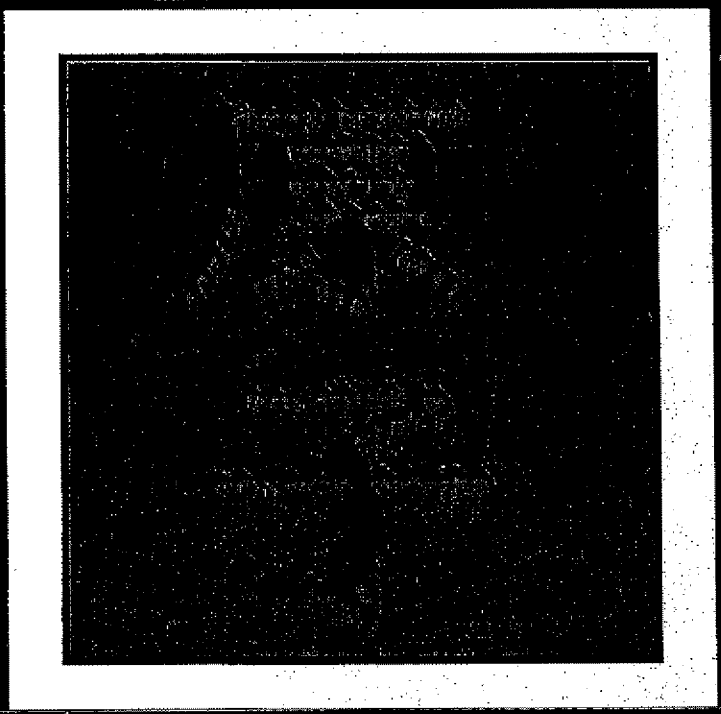
102. (Previously presented). The device of claim 97, wherein the reservoirs are microfabricated, at least one of the reservoirs contains drug or diagnostic molecules, and the device is adapted for implantation into a patient.

103. (Previously presented). The device of claim 77, wherein the reservoirs are fabricated using microfabrication techniques to define said reservoirs.

APPENDIX 2 – EVIDENCE

Marc J. Madou, Fundamentals of Microfabrication: The Science of Miniaturization 484-86 (CRC Press, 2d ed. 2002).

Marc J. Madou



Fundamentals of MICROFABRICATION

The Science of Miniaturization

Second Edition

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Marc J. Madou

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On the cover: Kanji character for "atom," by Lutz and Eigler, IBM, Almaden. An example of manipulation/mechanosynthesis of iron atoms on a Cu surface with an STM. (Courtesy of D. Eigler.)

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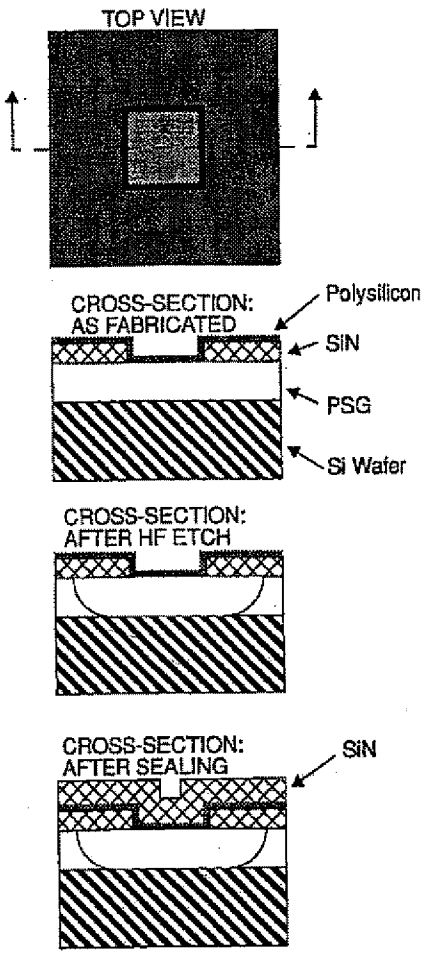


Figure 8.11 Schematic of etch access window design, operation, and sealing. (After Lebouitz et al., 8th Int. Conf. on Solid-State Sensors and Actuators, Transducers '95, Stockholm, Sweden, 224–27, 1995.[46])

arrays of 30 caps. The HEXSIL mold wafer is reusable. An example of a transferred encapsulation cap is shown in the SEM micrograph in Figure 8.13C.

Many of the newfound ways of hermetically sealing and bonding different layers and making contacts between them increasingly interest IC manufacturers. An important opportunity for micromachinists is to transfer the developed 3D machining technologies to the newest generations of 3D ICs.

Bonding

Field-Assisted Thermal Bonding

Field-assisted thermal bonding, also known as *anodic* bonding, *electrostatic* bonding, or the *Mallory process*, is commonly used for joining glass to silicon. The main utility of the process stems from the relatively low process temperature. Since the glass and Si remain rigid during anodic bonding, it is possible to attach glass to Si surfaces, preserving etched features in either the glass or the silicon. This method is mostly applicable to wafer-scale die bonding (L1).

A bond can be established between a sodium-rich glass, say Corning #7740 (Pyrex), and virtually any metal.[59] Besides Pyrex, Corning #7070, soda lime #0080, potash soda lead #0120, and aluminosilicate #1720 are suitable as well.[60] In the case of Si, Pyrex is most commonly used. Bonding can be accomplished on a hot plate in atmosphere or vacuum at temperatures between 180 and 500°C. Typical voltages, depending on the thickness of the glass and the temperature, range from 200 to 1000 V. The operating temperatures are near the glass-softening point but well below its melting point, as well as below the sintering temperature of standard AlSi metallization. At the most elevated temperatures, the wafers are bonded in 5 to 10 min, depending on voltage and bonded area.[60] Compared with Si fusion bonding (see below), anodic bonding has the advantage of being a lower-temperature process with a lower residual stress and less stringent requirements for the surface quality of the wafers. Figure 8.14 represents a schematic of an anodic bonding setup. Generally, one places a glass plate on top of the Si wafer and makes a pinpoint contact to the uppermost surface of the glass piece, which is held at a constant negative bias with respect to the electrically grounded silicon. The bonding is easy to follow. Looking through the glass, the bonded region moves from the contact cathode pinpoint outward and can be detected visually through the glass by the disappearance of the interference fringes. When the whole area displays a dark gray color, the bonding is complete. A constant current, instead of constant voltage, could also be used but is avoided, since dielectric breakdown may occur after the bonding is complete and the interface becomes an insulator (see bonding mechanism below). The contacting surfaces need to be flat (surface roughness $R_a < 1$ μm) and dust free for a good bond to form. The native or thermal oxide layer on the Si must be thinner than 200 nm. The thermal expansion coefficients of the bonded materials must match in the range of bonding. In Figure 8.15, we show the thermal expansion coefficient of Si and Pyrex as function of temperature (see also Figure 4.27).[61]

Above 450°C, the thermal properties of the materials begin to deviate seriously; therefore, the process should be limited to 450°C. One also would expect that Si would be under compression for seal temperatures below 280°C and under tension for temperatures in excess of 280°C.[61] Wafer curvature measurements indicate, however, that the transition from concave 7440 glass/Si sandwiches (Si under compression) to convex sandwiches (Si under tension) lies around a seal temperature of 315°C.[61,62] This indicates that other non-negligible, stress-inducing effects add an additional compressive component. As we learned before, for most applications tensile stress is preferred over compressive stress, and a considerable safety margin toward higher bonding temperatures must be respected to avoid buckled Si membranes and bridges.

The anodic bonding mechanism is not yet completely understood. Electrochemical, electrostatic, and thermal mechanisms and combinations thereof have been suggested to explain bond formation, but the dominant mechanism has not been clearly defined. It is suggested that, at elevated temperatures, the glass becomes a conductive solid electrolyte, and the bonding results through the migration of sodium (Pyrex contains approximately

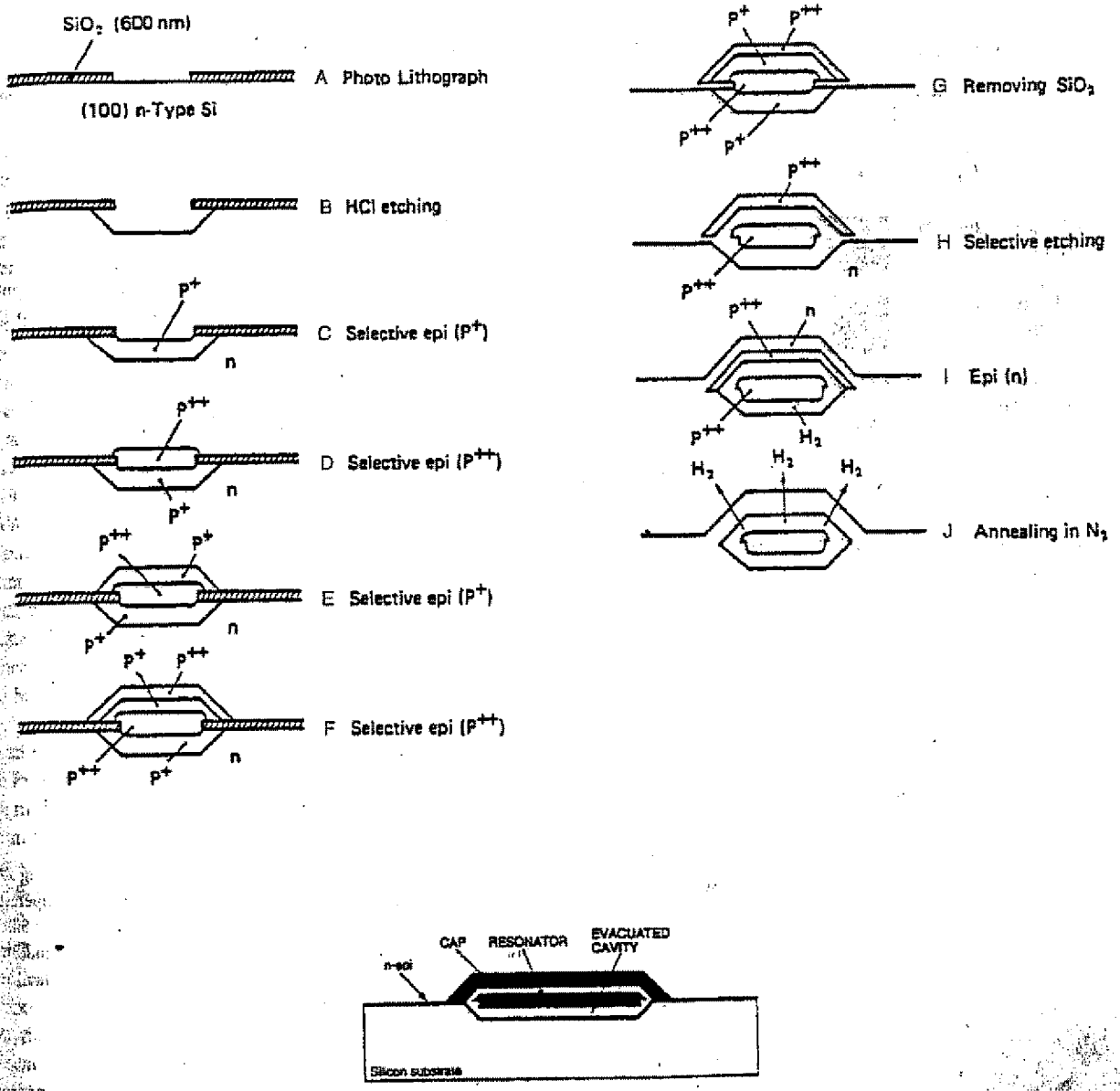
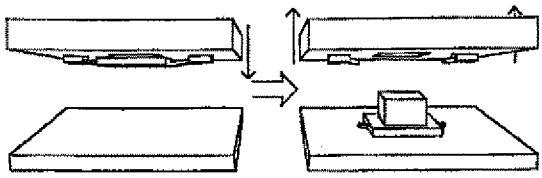


Figure 8.12 Epilayer-based fabrication process of a vacuum-encapsulated resonant beam. Process from (B) to (F) is carried out in one batch epitaxial process. (After Ikeda et al., *Sensors and Actuators A*, A21, 146–50, 1990.[56])

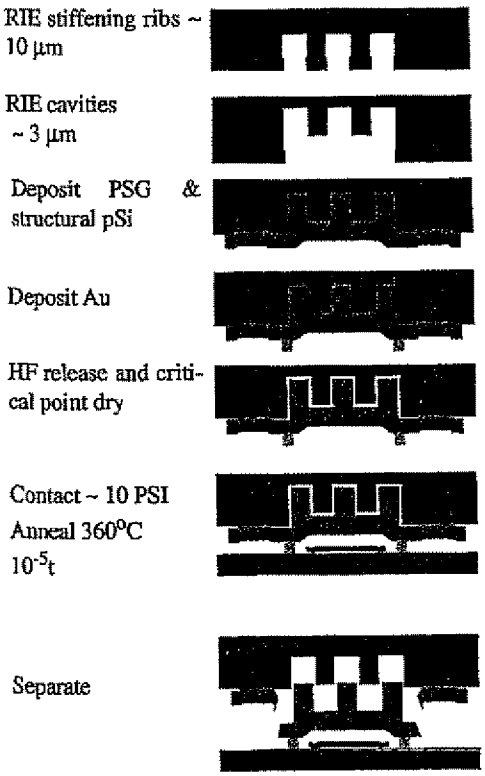
5% sodium) toward the cathode. As it moves, it leaves a space charge (bound negative charges) in the region of the glass/silicon interface. Most of the applied voltage drop occurs across this space charge region, and the high electrical field between the glass and Si results in an electrostatic force that pulls the glass and Si into intimate contact. The elevated temperatures result in covalent bonds forming between the surface atoms of the glass and the silicon. A good quantitative discussion on the many important effects in anodic bonding is by Anthony.[63]

Field-assisted bonding has also been applied to bond GaAs to glass. Corning #0211 is used at 360°C, and a bias of 800 V is applied for 30 min to complete the bonding process. It is well known that GaAs forms very poorly adhering oxides, leading to poor anodic bonding; prebake of the glass at 400°C for 15 hr in a reducing atmosphere (H_2 and N_2) is reported to lead to better bonding.[58] Von Arx et al. bonded glass capsules to a smooth poly-Si surface to form a hermetically sealed cavity large enough to contain hybrid circuitry of a biocompatible implant.[64]

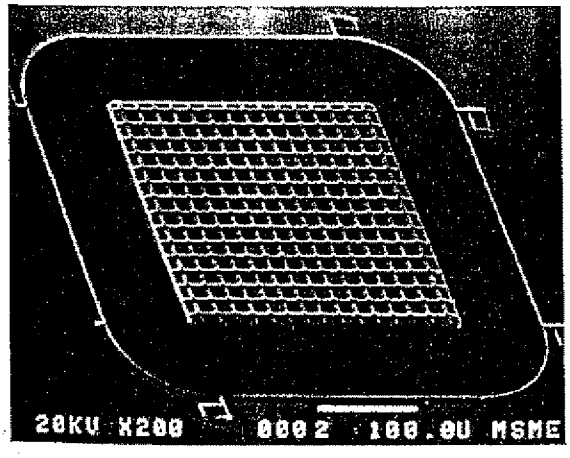
The high electrical field and the migration of sodium make anodic bonding of glass plates to Si a rather difficult technology. The mismatch in thermal expansion coefficient between the glass and the Si causes both thermally induced and built-in mechanical stress. In addition, the viscous behavior of the glass results in degraded long-term stability of the components. As a result of these problems, several modifications of the basic technology have been introduced (see below). A typical commercial instrument for anodic bonding is from Electronic Visions Co.'s 500 Series-Wafer Bonding Systems (e.g., the EV560).



A



B



C

Figure 8.13 Wafer-to-wafer transfer of encapsulation structures. (From Hok et al., *Appl. Phys. Lett.*, 43, 267–69, 1983.[58] Reprinted with permission.) (A) Principle of the wafer-to-wafer transfer method of encapsulation caps. (B) Fabrication of the tethered caps in a HEXSIL process. (C) SEM micrograph of a transferred cap.[57] (Courtesy of Dr. M. Cohen, University of California, Berkeley.)

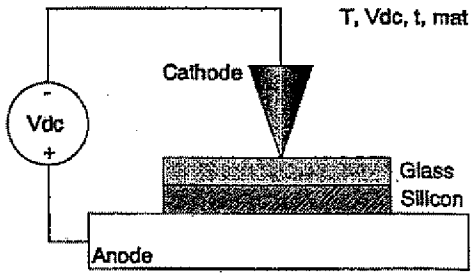


Figure 8.14 Principle sketch of anodic glass-to-Si bonding. Control parameters are temperature (300 to 400°C), bias voltage (700 to 1200 V), time (~2 min), and materials (glasses, Si, SiO_2).

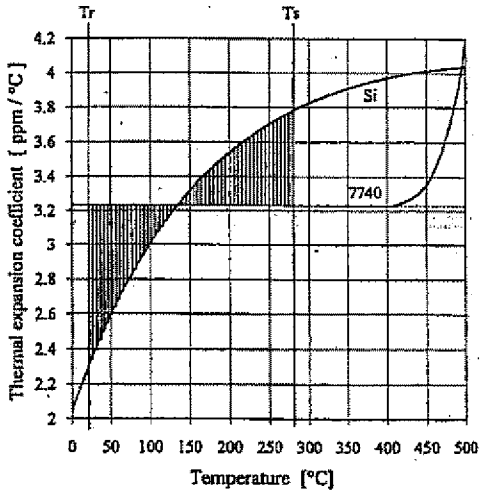


Figure 8.15 Thermal expansion coefficients of Si and Corning 7740 Pyrex. Tr = room temperature; Ts = seal temperature. The temperature Ts is a variable. (After E. Peeters, "Process Development for 3D Silicon Microstructures with Application to Mechanical Sensor Design," Ph.D. thesis, Catholic University of Louvain, Belgium, 1994.[61])

Field-Assisted Thermal Bonding Modifications

The pinpoint method for anodic bonding, as illustrated in Figure 8.14, requires a very high bias voltage and a long period of time to bond areas far removed from the cathode point, since the electrical field in the glass substrate diminishes fast as the distance from the pinpoint cathode increases. At NEC, a Ti mesh bias electrode is deposited over the whole glass wafer to accomplish faster bonding. Because of the mesh assistance, the whole wafer may be Si bonded at 400°C and 600 V in less than 5 min, compared with over an hour at the same temperature and voltage without the mesh.[65]

Another modification of anodic bonding by Sander[66] involves deposition of intermediate layers of Si dioxide and aluminum to screen the underlying Si from harm from the high electrical fields. First, Si dioxide is thermally grown on the Si surface. Then, a layer of aluminum is deposited on the oxide surface. Finally, a piece of glass is bonded to the aluminum. This technique produces a good hermetic seal, but the soft aluminum

APPENDIX 3 – RELATED PROCEEDINGS

None.